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EXAMINER				
HORNBERGER, JENNIFER LEA				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,014

Applicant(s)

KUHNS ET AL.

Examiner

JENNIFER L. HORNBERGER

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Objections

1. Claims 8-24 are objected to because of the following informalities: Claims 8-24 depend, directly or indirectly, from claim 4 which has been canceled. Appropriate correction is required. For examination purposes, it has been assumed that claims that depend directly from claim 4 are intended to depend from claim 1 because claim 4 was incorporated into claim 1.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 9-12, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788) in view of Pena (US 5,178,133).

Regarding claim 1 and 9-11, Ewerhardt et al. disclose a diagnostic device for pathologies of naturally occurring tubular anatomical structures comprising: a tubular elongated structure (10) developing between a proximal end and a distal end and being adapted to be inserted in the tubular anatomical structure, means for locally dilating (12) the walls of the tubular anatomical structure being associated with the distal end of said elongated structure, said means for locally dilating comprising a plurality of petals (12), wherein each petal comprises an arm which can broaden into a curved surface has an asymmetric conformation with respect to the respective arm (Figures 1 and 2), the petals being movable between a closed position (Fig. 1), wherein the petals overlap each other (Fig. 1), for the introduction of the device and at least one open position (Fig. 2) for the viewing and evaluation of the pathology, control means (21) being associated to the proximal end of the elongated structure, said control

means being operatively connected to said means for locally dilating in order to move them between the closed position and the open position, and vice versa (col. 3, ln. 47-51), said means for locally dilating having a rounded non-traumatic tip. Ewerhardt et al. fail to disclose a continuous membrane. Pena discloses a means for locally dilating (12) comprising a continuous transparent elastic membrane (34) externally covering dilating arms (12) for allowing the surgeon optimal viewing of the surgical field (see abstract). It would have been obvious to one of ordinary skill in the art to modify Ewerhardt et al. to include a continuous transparent elastic membrane externally covering the petals to evenly dilate the surrounding tissue in the surgical field as suggested by Pena. Ewerhardt et al. in view of Pena disclose the membrane external to the petals when the petals are overlapping in the closed position.

Regarding claim 12, Ewerhardt et al. disclose said elongated structure comprises an inner tube (21) and an outer tube (10) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals (col. 3, ln.15-19).

Regarding claim 20, Ewerhardt et al. disclose said petals (12) are formed as one piece with said outer tube (10; Fig. 1).

Regarding claim 21, Ewerhardt et al. disclose each petal (12) couples with a portion of said inner tube (21) forming a unidirectional guide adapted to close or open the petals subsequent to the translation of the inner tube relative to the outer tube and the petals (Fig. 2).

Regarding claim 22, Ewerhardt et al. disclose each petal (12) comprises a longitudinally extending rib (17) and wherein said inner tube (21) comprises a distal flange (15) provided with openings (16) adapted to couple with respective ribs (17) of said petals (col. 2, ln. 105-120).

Regarding claim 23, Ewerhardt et al. fail to disclose wherein said rib (17) has a T-shaped cross-section and wherein said openings has a C-shaped cross-section suitable to

couple with the cross-section of a respective rib. It would have been an obvious matter of design choice to give the rib a T-shaped cross section and the openings of the inner tube of the distal flange a C-shaped cross section, since applicant has not disclosed that the particular coupling solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the ribs and the openings having any shaped cross-sections which fit together.

4. Claim 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788) in view of Pena (US 5,178,133) as applied to claim 1 above, and further in view of Wallace (US 2,621,651). Ewerhardt et al. fail to disclose a means of viewing adapted to be associated with the elongated tubular structure and to reach the tract of the tubular anatomical structure. Wallace et al. disclose a dilating instrument locally dilating tubular anatomical structures, the dilator comprising an elongated means of viewing (40) associated with a hollow elongated tubular member for viewing the dilated area. It would have been obvious to one of ordinary skill in the art to modify the dilation tool of Ewerhardt et al. to comprise a means of viewing associated with the hollow elongated tubular member as suggested by Wallace et al. to allow the surgeon to view the surgical site.

5. Claim 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788) in view of Pena (US 5,178,133) as applied to claims 4 or 12 above, and further in view of Bertolero et al. (US 2005/0159645).

Ewerhardt et al. fail to disclose a petal and outer surface of the outer tube comprise at least one detection element or marker. However, Bertolero et al. disclose a detection element or marker on an outer sheath (paragraph 8) for determining the location in the body. It would have been obvious to provide a detection elements or radiopaque marker on the outer tube and/or on at least one petal to allow the location of the device in the body to be determined.

6. Claims 14-19 and 24, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788) in view of Pena (US 5,178,133) as applied to claim 12 above, and further in view of Sijp (DE 19828099 A1).

Regarding claims 14-16, Ewerhardt et al. in view of Pena fail to disclose an the inner tube has an annular groove adapted to receive and draw an end of said petals, said outer tube having openings to receive said petals, and said outer tube comprising a notch suitable to be inserted inside an aperture of a respective petal. Sijp discloses a device for dilating a tubular anatomical structure comprising an elongated structure, petals for locally dilating the walls of the anatomical structure, the elongated structure comprises an inner tube (10) and an outer tube (1) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals (Fig. 4-5). Sijp discloses the inner tube (1) has an annular groove adapted to receive and draw an end of said petals (3; Fig. 3-5). Sijp discloses said outer tube (10) has openings to receive said petals (Fig. 3-5). Sijp discloses at an opening said outer tube (10) comprises a notch suitable to be inserted inside an aperture (4) of a respective petal (3). It would have been obvious to one of ordinary skill in the art to one of ordinary skill in the art to substitute the elongated tubular structure of Ewerhardt et al. with the elongated tubular structure of Sijp in order to achieve the same predictable result of opening and closing the petals through relative movement of the inner and outer tubes.

Regarding claims 17-19, Ewerhardt et al. in view of Pena fail to disclose said inner tube has a distal grooved length or a threaded length adapted to receive and draw an end of a petal comprising a toothed area, wherein at an aperture said outer tube has seats adapted to receive a pivot of a corresponding petal. Sijp discloses a device for dilating a tubular anatomical structure comprising an elongated structure, petals for locally dilating the walls of the anatomical structure, the elongated structure comprises an inner tube (10) and an outer tube (1) adapted to

internally receive said inner tube, said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals (Fig. 4-5). Sijp discloses said inner tube (1) has a distal grooved length or a threaded length adapted to receive and draw an end of a petal (3) comprising a toothed area (8; Fig. 3). Sijp discloses said outer tube (218) has openings to receive said petals (Fig. 4-5). Sijp discloses wherein at an aperture said outer tube (218) has seats (4) adapted to receive a pivot (8) of a corresponding petal (3; Fig. 3-5). It would have been obvious to one of ordinary skill in the art to one of ordinary skill in the art to substitute the elongated tubular structure of Ewerhardt et al. with the elongated tubular structure of Sijp in order to achieve the same predictable result of opening and closing the petals through relative movement of the inner and outer tubes.

Regarding claim 24, Ewerhardt et al. fail to disclose a holding body at the proximal end of the outer tube. Sijp discloses a device for dilating a tubular anatomical structure comprising an elongated structure, petals for locally dilating the walls of the anatomical structure, the elongated structure comprises an inner tube (10) and an outer tube (1) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals (Fig. 4-5). Sijp discloses a holding body (6) arranged at the proximal end of an outer tube and a holding body (6) arranged at the proximal end of said inner tube. It would have been obvious to one of ordinary skill in the art to one of ordinary skill in the art to substitute the elongated tubular structure of Ewerhardt et al. with the elongated tubular structure including the holding members of Sijp in order to achieve the same predictable result of opening and closing the petals through relative movement of the inner and outer tubes.

Response to Arguments

7. Applicant's arguments filed 07/31/2009 have been fully considered but they are not persuasive. Ewerhardt et al. in view of Pena disclose a transparent elastic membrane positioned

on the exterior of the petals, wherein the elastic membrane remains on the exterior when then petals are closed. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
11/04/2009

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734